

REMARKS/ARGUMENTS

Claims 1 and 2 were pending. Claims 1 and 2 have been amended. Therefore, upon entry of this amendment, which is respectfully requested, claims 1 and 2 will remain pending.

Applicants hereby request that the enclosed Substitute Specification be accepted in the place of the Specification filed June 24, 2005. The Substitute Specification is in compliance with 37 CFR § 1.125(b) and is hereby requested to be entered. The here attached Substitute Specification does not add new matter.

Claims 1 and 2 were objected to as lacking antecedent basis as set forth in the Office Action mailed October 24, 2006. Appropriate correction has been made by making amendments to the claims similar to those suggested by the Examiner.

Claim 2 has been rejected under 35 USC §112, second paragraph as being indefinite. Appropriate correction has been made by making amendments to the specification as outlined on Page 2 above.

Claims 1 and 2 have been rejected under 35 USC §102(b) as being anticipated by Pinchuk et al. (EP 0861638). Applicant respectfully traverses this rejection.

Claims 1 and 2 have been rejected under 35 USC §103(a) as being anticipated by Pinchuk et al. (EP 0861638). Applicant respectfully traverses this rejection.

Arguments for Rejection-35 U.S.C § 112

Claim 2 has been rejected under 35 USC §112, second paragraph as being indefinite. Appropriate correction has been made by making amendments to the specification as outlined on Page 2 above. The specification as amended more clearly explains that the diagrammatical view of the velocity profile of flow of blood shown on the right hand side of Figure 1 with the hemodynamic deflecting core 2 of the stent of the invention 4 represents the current disclosure. Further, the current disclosure is not directed to the diagrammatical view of the velocity profile of flow of blood shown on the left hand side of Figure 1 with the hemodynamic deflecting core 2. Thus, the amended specification also adds the language "and

without the hemodynamic deflecting core 2 (left side of the Fig 1)", to better explain previous disclosure of applicant.

Arguments for Rejection-35 U.S.C § 102(b)

Claims 1 and 2 have been rejected under 35 USC §102(b) as being anticipated by Pinchuk et al. (EP 0861638). Applicant respectfully traverses this rejection.

In Pinchuk, each of the modular elements juts out axially from the others. The elements are axially juxtaposed, superposed merely towards their extremities, so as to form a longitudinally extending complex structure. (See Fig. 12, 13, 14). It is argued that Pinchuk anticipates the claim language where the outer stent structure is the stent graft 300 of Pinchuk, the deflector is stent-graft 400 combined with stent-graft 500, the pair of filaments are sutures 401 and 501, and the gap is the longitudinal gap between the end of stent graft 300 and the mid-section 506 of stent-graft 500.

However, in Applicant's amended Claims 1-2, all the elements are braided together, they exist intrinsically as part of a same structure and extend parallel to each other along their respective full lengths, which correspond to the length of the full structure itself. As a result, the structure of applicant is distinctly unique from that disclosed in Pinchuk because the elements of the Pinchuk structure are not braided together as in applicant's disclosure. Further, nothing in Pinchuk is directed to the benefits of braiding such elements together. Applicant, on the other hand, directs newly amended Claim1 to a structure permanently linked along its full length to a central hollow braided core extending parallel to the outer peripheral stent structure acting as an inner braided hemodynamic flow deflector by at least a pair of filaments. According to applicants disclosure, Paragraph 34, page 6, when permanently linking such a structure in a multilayer braided luminal self-expanding stent, an increase of shear stress of the blood elongates endothelial cells in the direction of the flow and ultimately reducing or even eliminating intimal hyperplasia thickening. Nothing in Pinchuk anticipates such a construction or the resulting benefits therein.

Moreover, Pinchuk and the present invention are not even designed to achieve the same function. Pinchuk is to be used with an impervious graft material (see col. 1; lines 45-56) to canalize the flow of blood inside a lesion (e.g. aneurysm) in a blood vessel. This impervious graft material has to be slipped inside Pinchuk's structure so it is therefore impossible to introduce a further central core inside this structure.

Finally, the prominent aim of the present stent, as claimed, is to improve the shear stress along the walls of a vessel (see §0034, page 6 and §0041, page 8). This function cannot be achieved by Pinchuk, which is not in contact with the blood flow (due to the presence of the impervious graft material placed inside it).

The present invention is thus allowable in light of Pinchuk and applicant requests allowance of amended Claims 1-2.

Arguments for Rejection-35 U.S.C § 103(a)

Claims 1 and 2 have been rejected under 35 USC §103(a) as being obvious over Pinchuk et al. (EP 0861638). Applicant respectfully traverses this rejection.

In Pinchuk, each of the modular elements juts out axially from the others. The elements are axially juxtaposed, superposed merely towards their extremities, so as to form a longitudinally extending complex structure. (See Fig. 12, 13, 14). It is argued that applicant's disclosure is obvious over Pinchuk, where the outer stent structure as claimed is the stent graft 300 of Pinchuk, the deflector as claimed is stent-graft 400 combined with stent-graft 500, the pair of filaments as claimed are sutures 401 and 501, and the gap as claimed is the longitudinal gap between the end of stent graft 300 and the mid-section 506 of stent-graft 500.

However, in Applicant's amended Claims 1-2, all the elements are braided together, they exist intrinsically as part of the same structure and extend parallel to each other along their respective full lengths, which correspond to the length of the full structure itself. As a result, applicant's structure is distinctly unique from that disclosed in Pinchuk because the elements of the Pinchuk structure are not braided together as in applicant's disclosure. Further, nothing in Pinchuk is directed to the benefits of braiding such elements together. Applicant, on the other hand, directs newly amended Claim1 to a structure permanently linked along its full

length to a central hollow braided core extending parallel to the outer peripheral stent structure acting as an inner braided hemodynamic flow deflector by at least a pair of filaments. According to applicants disclosure, Paragraph 34, page 6, when permanently linking such a structure in a multilayer braided luminal self-expanding stent, an increase of shear stress of the blood elongates endothelial cells in the direction of the flow and ultimately reducing or even eliminating intimal hyperplasia thickening. Nothing in Pinchuk suggests solving such a problem nor are such unexpected results predicted in the Pinchuk disclosure.

Moreover, Pinchuk and the present invention are not even designed to achieve the same function. Pinchuk is to be used with an impervious graft material (see col. 1; lines 45-56) to canalize the flow of blood inside a lesion (e.g. aneurysm) in a blood vessel. This impervious graft material has to be slipped inside Pinchuk's structure so it is therefore impossible to introduce a further central core inside this structure.

Finally, the prominent aim of the present stent, as claimed in applicant's disclosure, is to improve the shear stress along the walls of a vessel (see §0034, page 6 and §0041, page 8). This function cannot be achieved by Pinchuk, which is not in contact with the blood flow (due to the presence of the impervious graft material placed inside it).

Pinchuk explicitly describes (see i.e. claim 1) a modular stent-graft system, which is the very opposite of the teaching of the present invention because the very notion of a modular system is that the benefits of a singular structure is not contemplated. However, in applicant's present invention, the central core, links and the outer stent structure form a single structure specifically directed to the benefits of such a structure, namely contact with the blood flow and the resulting increase of velocity of the blood along the inner wall, resulting increase in shear stress of the blood, and the ultimate reduction of intimal hyperplasia thickening. Nothing in Pinchuk suggests such benefits nor is there any motivation to produce the benefits found in applicant's disclosure. One skilled in the art cannot therefore deduce applicant's present structure from the teaching of Pinchuk. The present structure is thus not obvious with respect to Pinchuk.

Applicant therefore respectfully requests the allowance of amended claims 1-2.

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PATENT

REMARKS

The attached Substitute Specification and amendments to the claims do not add new matter.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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